ALEC "Drug Liability Act	**Wisconsin LRB 2890**
Section 3. **The manufacturer or seller of a drug is not liable for punitive damages** if the drug alleged to cause harm either:	(2) LIABILITY OF MANUFACTURER OR SELLER; STRICT LIABILITY. Except as provided in sub. (4), a **manufacturer or a seller of a drug or device is immune from civil liability for any claim based on strict liability** for a defect in the design of a drug or device if the drug or device
(A**) Was manufactured and labeled in relevant and material respects** in accordance with the terms of an approval or license issued by the **Federal Food and Drug Administration** under the Food, Drug, and Cosmetic Act (21 United States Code Section 301, et seq.) or the Public Health Service Act (42 United States Code Section 201 et seq.) or	**was approved for safety and efficacy by the federal food and drug administration** at the time the drug or device left the control of the manufacturer or seller. A drug or device approved pursuant to the procedures under section 510 (k) of the federal Food, Drug and Cosmetic Act, 21 USC 360, shall not be considered approved for safety and efficacy by the federal food and drug administration for the purposes of this subsection.
(B) Is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, **including packaging and labeling regulations.**	(3) LIABILITY OF MANUFACTURER OR SELLER; FAILURE TO WARN. Except as provided in sub. (4), a manufacturer or a seller of a drug or device is immune from civil liability for any claim based on the failure to adequately warn of risk of a drug or device if labeling for the drug or device was made available to the consumer or to the person who prescribed the drug or device to the consumer **and the labeling was in compliance with the federal food and drug administration's applicable standards for labeling at the time the drug or device left the control of the manufacturer or seller.**
Section 4. Notwithstanding Section 2 (3?), punitive damages may be awarded **if the plaintiff proves, by clear and convincing evidence**, **that the defendant,** either before or after making the drug available for public use, **knowingly, in violation of applicable federal Food and Drug Administration regulations, withheld from or misrepresented to the Administration information** known to be material and relevant to the harm which the plaintiff allegedly suffered.	(4) EXCEPTION; FRAUD. Immunity under subs. (2) and (3) shall not extend to a claim brought against a manufacturer or a seller of a drug or device **if the federal food and drug administration determines that the manufacturer or seller committed a fraud against the federal food and drug administration** with regard to the product at issue in the claim.